UNITED STATES PATENT APPLICATION

FOR

METHOD AND APPARATUS FOR DETERMINING INJECTION DEPTH AND TISSUE TYPE

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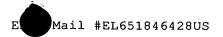Prepared By:

METHOD AND APPARATUS FOR DETERMINING INJECTION DEPTH AND TISSUE TYPE

FIELD OF THE INVENTION

This invention relates generally to injection devices,
and more particularly to injection devices guided by heat
dissipation characteristics of the body tissue through which
the device is being inserted.

BACKGROUND

It is increasingly important that a physician or
surgeon delivering substances, such as drugs, is able to
efficiently and accurately locate the desired target tissue
for effective delivery of the substance. This is
particularly true when the concentration of the substance
required at the target site cannot be safely or effectively
achieved by introduction of the substance to a location
remote from the target site. Currently, it is difficult to
determine injection depth and/or tissue type without
visually guiding the needle of an injection device or having
some other indication of the needle location within a
patient's body.

For example, fluoroscopy can be used to guide the
injection device, but fluoroscopy lacks the resolution and
sensitivity needed to accurately guide the injection device
into the desired tissue location. Alternatively,
electrocardiograph signals have been used when delivering
substances to ventricular tissues of the heart, but this
technique cannot be used throughout the entire body. In

addition, the use of imaging systems (e.g., ultrasonic, magnetic resonance, and optical) to view the injection device and surrounding tissue has been proposed, but the barriers to usage of such systems are large (e.g., including large capital investment, large space requirements, and ownership of intellectual property by others).

SUMMARY

A method and apparatus are disclosed for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue. In various embodiments, an elongate member such as a needle has at least one thermally conductive heating element mounted thereon. The heating element comprises material whose electrical resistance changes in response to a change in temperature. In addition, the apparatus includes an anemometry circuitry interface electrically coupled to the heating element so that the anemometry circuitry can measure the heat dissipation characteristics of the tissue environment in which the heating element is disposed.

DESCRIPTION OF THE DRAWINGS

Various embodiments are illustrated by way of example and not by way of limitation in the figures of the accompanying drawings in which like references indicate similar elements. It should be noted that references to "an", "one", or "various" embodiments in this disclosure are not necessarily to the same embodiment, and such references mean at least one.

Figure 1 is an embodiment of a heating element coupled to a needle.

Figure 2 is an electrical schematic of anemometry circuitry according to an embodiment.

Figure 3 shows the needle structure of **Figure 1** disposed within a blood stream.

5   **Figure 4** shows the embodiment of **Figure 3** disposed partially in a vessel wall and partly in the blood stream.

Figure 5 shows the device of **Figure 4** disposed almost entirely within the vessel wall.

Figure 6 is a graph which shows the voltage output of 10   an embodiment as it varies over time during the insertion shown in **Figures 3-5**.

Figure 7 shows an embodiment having multiple heating elements disposed on a needle such that one sensor is within the vessel wall and one sensor is disposed within the blood 15   stream.

DETAILED DESCRIPTION

The various embodiments described herein use heat dissipation characteristics of tissue to determine injection depth and/or tissue type. In the following description, for 20   purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the various embodiments. It will be apparent, however, to one skilled in the art that the various embodiments may be practiced without some of these specific details. The 25   following description and the accompanying drawings provide examples for the purposes of illustration only. However, these examples should not be construed in a limiting sense as they are merely intended to provide exemplary embodiments, rather than to provide an exhaustive list of 30   all possible implementations.

Referring now to **Figure 1**, device 10 is shown which comprises cylindrical needle 12 having a lumen therethrough

with opening 14 at a distal end to access a desired area
within the body.   Among other functions, needle 12 can be
used to deliver a substance, extract a substance, or
otherwise used to puncture tissue.   Examples of substances
that may be delivered include drugs, pharmaceutical agents,
fluids, proteins, polypeptides, gene therapy material, cell
therapy material, and deoxyribonucleic acid ("DNA").

The dimensions of needle 12 will vary depending on the
application.   For instance, needle 12 can be designed for
use with an intracardiac catheter to access a patient's
atria or ventricles of the heart via a patient's vascular
system, for use with an intravascular catheter to access a
patient's vascular system, for percutaneous use (e.g.,
puncturing the skin), and for generally accessing blood-
filled cavities and vessels (e.g., blood volumes).

Specifically, if needle 12 is to be used with an
intracardiac catheter, the outer diameter of needle 12 is
preferably between 0.065 inches (16 gage) and 0.013 inches
(29 gage).   In this regard, the gage sizes of hypodermic
needle stock are relatively standard in the industry and
refer to the outer diameter of the needle.   The inner
diameter will vary depending on the wall type.   For
intravascular catheter use, needle 12 will preferably have
an outer diameter between 0.032 inches (21 gage) and 0.010
inches (31 gage).   For percutaneous use, needle 12 can be
any size suitable for a particular insertion location and
the type of material to be injected or withdrawn.   However,
the most useful size range of needle 12 for percutaneous use
would have an outer diameter between 0.134 inches (10 gage)
and 0.009 inches (32 gage).   Despite the given size ranges
for each application, it is contemplated that sizes outside
of the given ranges can be used.

In addition, device 10 includes heating element 16

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coupled to an exterior portion of needle 12. Heating

element 16 will have approximately the same diameter size

constraints as needle 12 listed above for each application.

This is due to the fact that a heating element which has an

5   outer diameter substantially larger than the outer diameter

of the needle could create problems when inserting and

extracting device 10. Regarding the length of heating

element 16, it is preferred that the length be between 0.010

inches and 0.400 inches. However, lengths outside of this

10   range could also be used.

In various embodiments, heating element 16 comprises

material whose electrical resistance changes in response to

a change in temperature. Specifically, heating element 16

is constructed with a controlled temperature/resistance

15   relationship. In various embodiments, heating element 16 is

constructed of tungsten or platinum wire or a thin metallic

film. These materials have a resistance which increases as

the temperature increases. However, heating element 16 may

be constructed of other materials such as those used in

20   thermistors and other devices that exhibit changes in

electrical resistance in response to a change in

temperature.

Device 10 additionally includes first electrically

conductive lead 20 electrically coupled to a first end of

25   heating element 16 and second electrically conductive lead

22 electrically coupled to a second end of heating element

16 to serve as an interface with anemometry circuitry. In

other embodiments, an alternative anemometry circuitry

interface could be used. Although anemometry circuits are

30   generally used to measure flow rates of fluids, the various

embodiments disclosed herein use anemometry circuitry to

measure heat dissipation (e.g., flow of thermal energy) from

heating element 16.

Although the embodiment shown utilizes cylindrical
needle 12 to mount heating element 16, other embodiments
contemplate other elongate members (that may be non-
cylindrical) so long as they are suitable for insertion into
5   a body. For example, the elongate member could be a thin
rod (with or without opening 14 and with or without a
sharpened distal end). Furthermore, opening 14, if present,
could be disposed more proximally on needle 12, which would
allow for heating element 16 to be disposed distal to
10   opening 14. Such a configuration would advantageously
provide for heat dissipation measurement in situations in
which tissue just distal of the desired injection depth
provides a more reliable or larger signal change/reading.

Figure 1 depicts heating element 16 as a wire. The
15   wire should be large enough to conduct a sufficient amount
of current but small enough to be effectively mounted on
needle 12. It is worth noting that in various embodiments,
heating element 16 can comprise at least one of a wire, a
film, and a thermistor material.

20   In one embodiment, heating element 16 has a length that
is approximately equal to or less than the known thickness
of a targeted tissue (accounting for the tissue penetration
angle of device 10) whose heat dissipation characteristics
are to be measured by device 10. Embodiments which include
25   this feature are able to more discretely measure heat
dissipation characteristics and detect differences in such
characteristics than embodiments with heating elements 16
which are longer and, therefore, have no penetration depth
at which heating element 16 is surrounded by only the
30   targeted tissue.

In the embodiment shown in **Figure 1,** heating element 16
is shown having a coil portion 18 wrapped around needle 12
with covering 24 disposed over coil portion 18. Covering 24

is adhered to needle 12 or formed as an integral part of needle 12. Covering 24 protects heating element 16 and provides for a smooth transition with the surface of needle 12 to make insertion of needle 12 into tissue easier and

5   less traumatic.

Covering 24 can be made of a non-conductive material to insulate the patient from electrical current flowing through coil portion 18. Moreover, the wire that forms coil portion 18 may also be coated with an electrical insulator. Thus,

10   either or both methods of providing electrical insulation described herein may be used.

Figure 1 shows heating element 16 as a coiled wire. Other wire configurations are also suitable. For example, heating element 16 can be formed by placing the center of

15   the wire near the distal end of heating element 16 and winding each end 20 and 22 in opposite directions around needle 12 towards the proximal end of needle 12. Alternatively, the wire may be wound in a zigzag pattern, proximally and distally, back and forth in a desired area.

20   Alternatively, heating element 16 can be formed by mounting the wire within a groove or a plurality of grooves formed within the surface of needle 12.

In addition to wire configurations, heating element 16 can be formed by sputtering a thin film of metal over a

25   masked insulator (masked to lay down the desired heating element metal configuration), removing the mask, attaching the conductors, and coating the remaining metal connections with an insulator (e.g., a dielectric material). Moreover, a photo-etching process, similar to that used in the

30   microelectronics industry, could be used to remove metal from needle 12 in the desired configuration.

Heating element 16 can be mounted on needle 12 such that distance 26 (from the distal end of opening 14 to the

proximal end of heating element 16) is substantially
equivalent to a desired injection depth. Heating element 16
may be enclosed or mounted on or in a suitable assembly,
syringe, or catheter to aid in the insertion, advancement,

5   orientation, and delivery of device 10 to the desired
position within the body prior to injection.

        In addition, the proximal end of device 10 may be
provided with suitable electrical connections to external
circuitry and/or instrumentation (not shown) as well as

10 fluid connections to force the injectant through device 10.
Common catheter assemblies provide such connections.

        In various embodiments, needle 12 can be comprised of
material which is not electrically conductive (e.g.,
ceramic) or material which is electrically conductive (e.g.,

15 stainless steel). It is worth noting that ceramic needles
advantageously increase response time and sensitivity of
heating element 16 due to the reduced thermal mass and
thermal conductivity of ceramic. However, electrically
conductive materials have electrical connection advantages,

20 which can simplify device design. For instance, in
embodiments in which a portion of needle 12 is electrically
conductive, heating element 16 can be connected to
anemometry circuitry by (i) first electrically conductive
lead 20 electrically coupled to a first end of heating

25 element 16 and (ii) a conductive portion of needle 12
coupled to a second end of heating element 16.

        If a high thermal mass needle (e.g., stainless steel)
is used, a thermal insulator can be disposed between heating
element 16 and needle 12 to minimize any reduction in

30 response time and sensitivity of heating element 16 caused
by needle 12.

        Regardless of the construction and materials used to
construct heating element 16, device 10 can have more than

just a single heating element 16, as shown in **Figure 1.** For
instance, if a plurality of heating elements 16 are mounted
on needle 12 and operated separately and/or in groups,
multiple penetration depths/tissue types can be
5   controlled/identified. In addition, a single penetration
depth can be more effectively controlled with an embodiment
which utilizes a plurality of heating elements 16.

Turning now to **Figure 2,** an embodiment of anemometry
circuitry is shown. In the embodiment shown, the anemometry
10   circuitry is configured to measure the heat dissipation
characteristics of an environment in which heating element
16 is disposed. The anemometry circuitry is electrically
coupled to heating element 16 shown in **Figure 1.**
Specifically, a first end of heating element 16 is
15   electrically coupled to first junction 42 of bridge circuit
28, and a second end of heating element 16 is electrically
coupled to node 41 of bridge circuit 28.

Figure 2 is a simplified representation of a
temperature controlled hot wire or hot film anemometer
20   system. Although there are many ways to operate an
anemometer system (e.g., constant current or constant
voltage), temperature controlled is preferred because the
various embodiments are intended to be used within the body.
Control over the temperature of heating element 16 can
25   advantageously avoid tissue damage caused by temperature.
In addition, signal level changes in response to the heat
dissipation characteristics of the environment in which
heating element 16 is disposed will be maximized.

The anemometry circuitry shown in **Figure 2** includes
30   balancing bridge circuit 28, controlled amplifier 30, and
signal amplifier 32. Although other designs and
configurations for the circuitry could be used, this
simplified representation is included for ease of

discussion. Bridge circuit 28 is comprised of heating

element 16, a system controlled variable resistor 34 and two

fixed resistors 36 and 38. Heating element 16 acts as a

resistor within bridge circuit 28.

5   Bottom node 41 of bridge 28 is connected to ground

(e.g. 0 volts). Thus, when a voltage is applied at top node

40 of bridge 28, current will flow through heating element

16, causing a dissipation of power. Due to the material and

construction of heating element 16, the dissipated power is

10   dissipated as heat. The heat will raise the temperature of

heating element 16 such that the temperature change will

cause a change in the resistance of heating element 16.

For the sake of simplicity, it is assumed that fixed

resistors 36 and 38 have the same resistance value.

15   Although this is not required, this assumption makes

explanation of the anemometry circuitry easier to

understand. As heating element 16 increases in temperature,

the resistance of heating element 16 also increases, causing

the voltage at first junction 42 (between heating element 16

20   and resistor 36) to increase.

Thus, if variable resistor 34 has a resistance value

adjusted by the circuitry to be equal to that of heating

element 16, then the voltage at second junction 44 (between

fixed resistor 38 and variable resistor 34) will be the same

25   as at first junction 42. When the voltages are equivalent,

bridge circuit 28 is understood to be "balanced". Thus,

once variable resistor 34 has been adjusted to have a

resistance value equal to that of heating element 16, any

changes to the resistance of heating element 16 (e.g.,

30   caused by changes in temperature) will cause the voltage at

junction 42 to change in the direction of and roughly in

proportion to the temperature change of heating element 16.

Thus, the voltage at first junction 42 would be either

higher or lower than the voltage at second junction 44.

Amplifier 30 is electrically coupled to bridge circuit 28 to sense the difference in voltage drop across heating element 16 and variable resistor 34 caused by the difference

5   between the resistance of heating element 16 and the resistance of variable resistor 34. Amplifier 30 receives power from positive Vsupply and is also coupled to ground. Amplifier 30 compares the voltages of positive input 46 and negative input 48. If positive input 46 is a higher voltage

10   than negative input 48, the positive difference between input 46 and input 48 is amplified and output through line 50.

It is worth noting that no voltage higher than positive Vsupply will be seen at output 50. If negative input 48 is

15   equal to or higher than positive input 46, then the voltage present at output 50 will be a low positive value (e.g., too low to cause significant heating of heating element 16). Amplifier 30 is able to compare the input voltages since positive input 46 is connected to second junction 44, and

20   negative input 48 is connected to first junction 42. Output 50 of amplifier 30 is connected to top node 40 of bridge circuit 28.

Focusing now on the interaction between amplifier 30 and bridge circuit 28, it is assumed that bridge circuit 28

25   is initially in a balanced condition. Thus, the voltage applied to top node 40 of bridge circuit 28 by output 50 of amplifier 30 is low, and heating element 16 is not being heated. Also, the resistance of heating element 16 is equal to that of variable resistor 34.

30   If the anemometry circuitry system raises the resistance of variable resistor 34, the voltage at junction 44 will exceed the voltage at junction 42. This, in turn, creates a positive voltage difference between positive input

46 and negative input 48. This positive voltage difference
causes output 50 to dramatically rise in voltage.

Output 50 is applied to top node 40 of bridge circuit
28, raising the current through heating element 16, which
5   causes the power (e.g., heat) dissipated by heating element
16 to increase dramatically. The increase in heat
dissipated by heating element 16 results in an increase in
the temperature of heating element 16.

When the temperature of heating element 16 nearly
10   reaches the temperature at which the resistance of heating
element 16 is the same as that of variable resistor 34, the
voltages at junctions 42 and 44 will be very close to equal.
In addition, output 50 applied to top node 40 of bridge
circuit 28 will begin to drop until an equilibrium is
15   reached. Upon reaching this equilibrium, heating element 16
will be heated to a temperature that correlates to a
resistance that is very close to that of variable resistor
34. With high amplification factors in amplifier 30, this
resistance difference can be made to be negligible.

20   Since the resistance/temperature relationship of
heating element 16 is known and heating element 16 now has
the same resistance as variable resistor 34, the temperature
of heating element 16 is also known. Thus, this interaction
allows the temperature of heating element 16 to be set by
25   adjusting the value of variable resistor 34 so long as
positive Vsupply can supply enough voltage/current to top
node 40 of bridge circuit 28 to sufficiently heat heating
element 16 to the desired temperature. It is worth noting
that the desired temperature is above ambient temperature of
30   heating element 16 and that output 50 is at some
intermediate voltage value between the maximum and minimum
values for which amplifier 30 is configured when heating
element 16 is heated above the ambient temperature.

Thus, output 50 is directly related to the heat
transfer environment of heating element 16. If that
environment carries heat away from heating element 16
rapidly, then output 50 will be a higher value than if that
5   environment carries heat away more slowly.

It is expected that these changes in output 50 may be
small. Thus, signal amplifier 32 is employed to increase
the size of the change to a level suitable for an associated
instrument (not shown) to sample, process, and display the
10   measurements in a suitable manner. Signal amplifier 32
operates similarly to controlled amplifier 30. However,
signal amplifier 32 is supplied with negative Vsupply,
instead of power supply ground. Thus, output 56 may vary
between the values of positive Vsupply and negative Vsupply
15   in response to the voltage difference of inputs 52 and 54.

If positive input 52 is a higher voltage than negative
input 54, then the positive difference between the two
inputs is amplified, and the amplified voltage is presented
at output 56. If positive input 52 is a lower voltage than
20   negative input 54, then the negative difference between the
two inputs is amplified, and the amplified negative voltage
is presented at output 56. It is worth noting that the
amplification factor for negative and positive differences
is the same.

25   Negative input 54 is connected to wiper 58 of system
controlled potentiometer 60. Potentiometer 60 is also
connected to positive Vsupply and power supply ground such
that, as wiper 58 is adjusted, the voltage at wiper 58 will
vary between zero and the voltage of positive Vsupply.

30   Assuming that heating element 16 is maintained at a
higher than ambient temperature, amplifier 32 behaves in the
following manner. Since voltage output 50 is connected to
positive input 52 of amplifier 32, input 52 is at some

intermediate positive voltage level. The anemometry
circuitry may then adjust wiper 58 such that negative input
54 is at or nearly at the same voltage as input 52. Thus,
voltage output 56 of amplifier 32 will be approximately

5   zero.

However, if heating element 16 is moved to an
environment that transfers heat more rapidly, positive input
52 (from output 50) will exceed negative input 54 (from
wiper 58), and output 56 of amplifier 32 will increase a

10   multiple of the actual increase seen at input 52 due to an
amplification factor of amplifier 32. If heating element 16
is moved to an environment that transfers heat less rapidly,
positive input 52 will be less than negative input 54, and
output 56 of amplifier 32 will have a negative value which

15   is a multiple of the actual decrease seen at input 52.

Although anemometry circuitry is generally used to
measure the flow velocity of fluid or gas, or, where the
dimensions of the flow conduit are known or constant, to
calculate flow rates, various embodiments described herein

20   use the detected differences in the heat dissipation
characteristics of different body tissues to determine
injection depth and/or tissue type. It is worth noting that
the embodiments disclosed herein should not be limited to
measuring the heat dissipation characteristics of tissues

25   since there are other materials within the body which are
not generally considered tissues but will still have
measurable heat dissipation characteristics. For instance,
spinal fluid and amniotic fluid are not considered tissues
but could have their respective heat dissipation

30   characteristics measured to determine injection depth or
material type.

Focusing now on exemplary heat dissipation
characteristics of different materials, atheroma is a

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degenerative accumulation of lipid-containing plaque on the innermost layer of a wall of an artery. For heat dissipation purposes, atheroma is generally a waxy substance with no blood flow. If device 10 were inserted into a layer

5   of atheroma, heating element 16 would only dissipate a negligible amount of heat.

Similarly, fat tissue does not have much blood flow, and therefore, heating element 16 inserted into fat tissue would experience a low heat dissipation rate. However, the

10   same heating element 16 inserted into muscle tissue, which has substantial blood flow, would experience a high heat dissipation rate, and if heating element 16 were inserted into a moving blood stream, the heat dissipation rate experienced by heating element 16 would be extremely high.

15   **Figures 3-6** demonstrate how device 10 with a single heating element 16 can be used to control the depth of penetration of needle 12 into the wall of a coronary artery to desired penetration depth 26. It is assumed that device 10 is inside a suitable catheter (not shown) at the desired

20   location, that the catheter is a relatively good thermal insulator, that heating element 16 is being driven at a temperature above blood temperature, and that the anemometry circuitry which drives heating element 16 is connected to heating element 16 and properly configured.

25   **Figure 6** shows a graph of voltage output 56 of amplifier 32 versus time. Before T_1, heating element 16 is inside the catheter (not shown). Since the catheter is assumed to be a relatively good thermal insulator, the drive voltage or current required to keep heating element 16 at a

30   stable temperature is low. Thus, output 56 of amplifier 32 is very negative. At time T_1, device 10 is rapidly moved out of the catheter and into blood stream 62 of the artery (**Figure 3**).

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Blood stream 62 carries away heat at an extremely high rate, which cools heating element 16 mounted on device 10 rapidly. Thus, output 56 rises rapidly to a maximum value and remains at the maximum value until T_2, when heating

5   element 16 has almost reached the set temperature (or resistance) again. At T_3, bridge circuit 28 reaches equilibrium with the new heat dissipation environment of blood stream 62. The line segment between T_3 and T_4 represents the new equilibrium level. This line segment is

10   shown as a straight line for simplicity, but in reality, this line segment would have oscillations due to changes in the velocity of blood stream 62 relative to heating element 16 during the cardiac cycle.

The line segment between T_4 and T_5 represents the

15   smooth continuous insertion of heating element 16 into artery wall 64 (**Figure 4**). Since artery wall 64 will be composed of atheroma, muscle tissue, connective tissue, and other surrounding tissues with low heat flow characteristics, artery wall 64 will be a better thermal

20   insulator than blood stream 62. Thus, output 56 will change in a negative direction until heating element 16 is completely within artery wall 64 at T_5. **Figure 5** shows device 10 inserted into artery wall 64 to desired penetration depth 26.

25   As discussed above, the line segment between T_4 and T_5 is shown as a straight line for simplicity, but in fact, the line segment will have the same cardiac cycle bumps as the line segment between T_3 and T_4. However, as more of heating element 16 is inserted into artery wall 64, the amplitude of

30   these cardiac bumps will decrease until heating element 16 is no longer in blood stream 62.

One drawback of the single heating element design is that if needle 12 were inserted further into artery wall 64,

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there would be little change in output 56 to alert the user
of the change in position. However, if second heating
element 17 were mounted just proximal to first heating
element 16 (**Figure 7**), then desired penetration depth 26
5　could be more easily determined. Assuming heating elements
16 and 17 are constructed in the same manner, desired
penetration depth 26 would be located when the greatest
difference in outputs 56 of each of the respective heating
elements was observed.

10　　　　If needle 12 were further inserted into artery wall 64,
output 56 of heating element 17 would decline toward the
value of output 56 for heating element 16. Conversely, if
needle 12 were withdrawn from artery wall 64, then output 56
of heating element 16 would increase toward the output 56 of
15　heating element 17. Thus, multiple heating elements allow
for monitoring the depth of penetration of needle 12 within
relatively close limits relative to any tissue interface
where the two interfacing tissues have sufficient difference
in heat dissipation characteristics and thickness relative
20　to the length of heating elements 16 and 17 to be
detectable.

　　　　As shown in **Figure 7**, multiple heating elements can be
constructed within a single heating element assembly. For
example, in the embodiment shown, heating element 16 and
25　heating element 17 are both disposed in covering 24. In
addition, only three electrical leads are required since
each heating element has a separate bridge circuit 28 (not
shown) connecting the heating element to ground (node 41 in
Figure 2). Thus, heating element 16 and heating element 17
30　share a lead to ground. In embodiments which use needle 12
as a conductive lead, needle 12 can be used as the ground
connection for all heating elements.

　　　　The embodiments disclosed herein can be operated by

much more complex and sophisticated circuitry and
instrumentation to filter, process, and detect the
differences in the heat dissipation characteristics of
different tissue types. For example, the temperature of
heating element 16 could be stepped in increments small
enough to avoid saturating amplifier 30 toward or away from
body temperature, using the rate of equilibrium
establishment to differentiate tissue types or boundaries in
a more rapid manner.

It is to be understood that even though numerous
characteristics and advantages of various embodiments have
been set forth in the foregoing description together with
details of structure and function of the various
embodiments, this disclosure is illustrative only. Changes
may be made in detail, especially matters of structure and
management of parts, without departing from the scope of the
various embodiments as expressed by the broad general
meaning of the terms of the appended claims.